

12

**EUROPEAN PATENT APPLICATION**

Application number: 85308391.3

Int. Cl.<sup>4</sup>: G 01 N 21/47, G 01 J 1/16

Date of filing: 18.11.85

Priority: 19.11.84 GB 8429211

Applicant: HOME DIAGNOSTICS, INC., 6 Industrial Way  
West, Eatontown New Jersey 07724 (US)

Date of publication of application: 28.05.86  
Bulletin 86/22

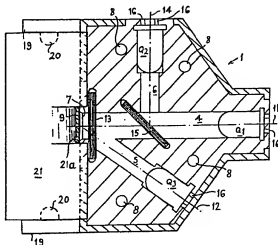
Inventor: Salem, Robert Joseph, 109 Glover Avenue,  
Norwalk CT 06850 (US)

Designated Contracting States: DE FR SE

Representative: Warren, Keith Stanley et al, BARON &  
WARREN 18 South End Kensington, London W8 5BU  
(GB)

**Reflectometer.**

A reflectometer has an optical chamber comprising a light source (Q1) for illuminating a test specimen (9) and a reflectance photosensor (Q3) responsive to light reflected from the test specimen to produce a reflectance signal corresponding to the reflectance of the specimen. The reflectance photosensor (Q3) is disposed along an optical path (5) having its optical axis (11) of the optical path (4) along which light is projected onto the test specimen by the light source (Q1) so that the photosensor (Q3) detects random reflections from the test specimen (9). The optical chamber may also include a reference photosensor (Q2), a beam splitter (15) arranged to reflect a minor fraction of the light emitted by the light source (Q1) onto the reference photosensor, and a drive circuit for the light source which is responsive to a control signal derived from the reference sensor (Q2) and which provides for pulsed operation of the light source so as to maintain the control signal generally at a constant level.



ACTORUM AG

BEST AVAILABLE COPY

REFLECTOMETER

1       The present invention relates to reflectometers  
and, more particularly, although not exclusively, to  
reflectometers used to monitor the colour change of a  
test strip in response to its reaction with a fluid  
5 specimen applied to the strip. For example, such  
reflectometers may be used to monitor the blood/glucose  
levels of diabetics by detecting the colour change of a  
test strip to which a blood specimen has been applied.  
Reflectometers used for this purpose are commonly  
10 referred to as "glucometers".

Ideally, a reflectometer as used, for example, to  
measure blood/glucose levels from reactive test strips,  
should give consistent reflectance measurements from  
standard reflectors regardless of temperature,  
15 humidity, or other environmental factors. It should  
also produce a consistent measurement for a given  
colour standard, regardless of a test strip's surface  
shine. Particularly, with dark colours, which absorb  
more light, the shine effect produced by directly  
20 reflected light does not allow accurate sensing of such  
colours.

Temperature effects on circuits and optical  
sensors have proved to be the single largest cause of  
reflectance errors and the most difficult of  
25 environmental variables to overcome. Hitherto,  
relatively low cost reflectometers have endeavoured to  
eliminate the temperature effects by having a user  
calibrate each time with a dark and light standard  
reflector or, at a minimum, with a light standard  
30 reflector allowing the dark standard to drift. It has

1    been found that using dark standards contributes very  
    little to overall accuracy. Since many users reject the  
    necessity of reflectance calibration every time before  
    use, many manufacturers have avoided this requirement  
5    by assuming that most measurements would be made at  
    about 25°C ambient. With this arrangement, users are  
    only required to check reflectance calibration  
    periodically. However, a check on the performance of  
    reflectometers presently marketed and having no  
10   reference systems, at temperatures of 15°C to 35°C,  
    shows that such units are subject to errors ranging  
    from 50% to 100%.

    In order for a reflectometer to provide accurate  
    readings, it is merely necessary for the reflectometer  
15   to detect the colour of a specimen or sample and not  
    the reflected image so that it is unnecessary to detect  
    directly reflected light, and shine effects can be  
    alleviated by detecting random or dispersed reflected  
    light. Accordingly, it is one object of the present  
20   invention to provide a reflectometer which detects  
    random reflections from a test strip or other specimen,  
    thereby alleviating errors produced by the shine effect  
    of directly reflected light.

    From one aspect, therefore, the invention  
25   provides an optical chamber for a reflectometer,  
    comprising at least one light source arranged to direct  
    light, along an associated first optical path to  
    illuminate a test specimen, and at least one  
    reflectance photosensor disposed along an associated  
30   second optical path having its optical axis inclined to  
    the optical axis of the first optical path and  
    intersecting the latter at or adjacent the test  
    specimen, whereby the photosensor detects random

1 reflections from the test specimen. The optical axis of  
the second optical path may be inclined at an angle of  
at least  $20^\circ$  to the optical axis of the first path and  
is, preferably, inclined at an angle of approximately  
5  $35^\circ$ .

With this invention, the reflectance sensor is  
offset from the optical axis of the first optical path,  
along which the light beam from the light source is  
projected onto the test specimen, so that whilst the  
10 overall amount of light received for a given  
reflectance is reduced, it is positioned out of the  
shine or halo area and the problem of surface shine,  
which may change true reflectance readings, especially  
of dark values, by as much as 2%, is reduced or  
15 eliminated. By alleviating shine effects, the  
reflectance measurement of high absorbing colours is  
improved and, in the case of glucometers, for example,  
the measurement of higher glucose concentrations, say  
in excess of 400 mg/dl, is more accurate.

20 The optical chamber may also include a reference  
photosensor associated with the or each light source  
and disposed along a third optical path, and means  
arranged to reflect a minor portion of the light  
projected by the associated light source along this  
25 third optical path and onto the reference sensor whilst  
transmitting a major portion of the light so as to  
impinge on the test specimen.

Conveniently, the or each light source is a light  
emitting diode (LED) and the sensors are photodiodes.

30 In one preferred embodiment of the invention  
designed for a glucometer, the reference sensor is  
disposed along a third optical path which has its axis  
substantially perpendicular to the axis of the first  
optical path and a beam splitter is arranged to reflect

1 a minor portion of the light emitted by the associated  
light source onto the reference sensor. A holder device  
is provided for locating a test strip along the first  
optical path with the plane of the strip disposed  
5 substantially perpendicular to the first optical axis,  
and a protective lens device is disposed across the  
first and second optical paths adjacent the position at  
which the test strip is located.

When LEDs and other light sources are initially  
10 excited with a constant current, the emitted light is a  
function of the temperature of the source. Light  
sources are generally more efficient when cold and the  
amount of light emitted decreases, as they warm up,  
until a steady state emission is reached. For example,  
15 as the junction of an LED heats up, less light is  
emitted for the same constant current. The same effect  
also holds true for ambient temperature. As ambient  
temperature increases, the efficiency of an LED or  
other light source decreases. Hence, less light is  
20 emitted for a given current as junction or operating  
temperature or ambient temperature increases.

Most glucometers solve the temperature problems  
of LEDs or other light sources by switching them on for  
a relatively long period, say, 30 to 60 seconds, before  
25 a measurement is made, thereby allowing them thermally  
to equilibrate. This requirement obviously causes the  
glucometers to consume unnecessary battery power for  
each measurement and thus battery life is reduced.

Accordingly, it is another object of the present  
30 invention to avoid the requirement for switching on the  
light source of a reflectometer for a long period  
before a measurement can be taken. Other objects are to  
alleviate errors caused by environmental conditions and  
eliminate the need to calibrate for reflectance.

1        From another aspect, therefore, the invention  
provides a reflectometer comprising at least one light  
source arranged to illuminate a test specimen, at least  
one reflectance sensor responsive to light reflected  
5 from a test specimen to produce a reflectance signal  
corresponding to the reflectance of the specimen, at  
least one reference sensor responsive to a fraction of  
the light emitted by the light source, and a drive  
circuit for the or each light source which is  
10 responsive to a control signal derived from the  
associated reference sensor and which operates the  
light source so as to maintain the control signal  
generally at a constant level.

Conveniently, the drive circuit for the light  
15 source comprises comparator means which compares the  
control signal derived from the reference sensor with a  
reference signal and operates the light source so as to  
maintain the control signal generally at a constant  
level, for example, the level of the reference signal.

20        Hence, with this invention, instead of applying a  
constant current to a light source, the light source  
may be forced to output the same voltage level  
regardless of ambient temperature or the temperature of  
the light source. This is achieved by successively  
25 switching the light source on and off to produce pulsed  
operation with a frequency and pulse width sufficient  
to keep the signals derived from the reference sensor  
at or in the region of a predetermined constant level  
independently of temperature, light source efficiency  
30 or reference sensor sensitivity. Consequently, the  
light source need only be switched on for a short  
period, for example, 1-2 seconds, to permit the  
reflectometer to produce a measurement of reflectance.

Preferably, the reflectometer includes means for

1 producing a digital reflectance signal corresponding to  
a reflectance sensor output. Such means may include an  
analog-to-digital (A/D) converter circuit which  
compares an analog reflectance signal derived from the  
5 reflectance sensor output with the aforementioned  
reference signal and produces a pulse train having a  
pulse rate or frequency corresponding to the analog  
reflectance signal. This resulting pulse or digital  
signal may readily be processed by a central processing  
10 unit, such as a microprocessor, to produce a  
measurement of the reflectance.

The or each reference sensor may be connected to  
amplifying means having an integrating circuit for  
integrating the output of the amplifier, and the  
15 control signal for the light source drive circuit may  
be derived from this amplifier output signal.  
Similarly, the or each reflectance sensor may be  
connected to amplifying means having an integrating  
circuit coupled to its output, and the reflectance  
20 amplifier output signal may be processed to produce the  
digital reflectance signal.

The output of the reference sensor amplifier may  
be connected to a voltage divider circuit for supplying  
an adjustable control signal to the light source drive  
25 circuit. The output of the reflectance sensor amplifier  
may be supplied to the A/D converter network via a  
fixed gain amplifier having one input connected to the  
reflectance amplifier output and another input  
connected to the voltage divider circuit associated  
30 with the reference sensor amplifier. The connection of  
the drive circuit to the voltage divider may be  
adjustable so as to set the light standard reflectance  
whilst the connection of the fixed gain amplifier to  
the divider may be used to adjust the dark standard

1 reference.

In order that the present invention may be more readily understood, reference will now be made to the accompanying drawings, in which:-

5 Figure 1 illustrates the optical chamber and associated test strip holder of a glucometer embodying the invention, the optical chamber being shown in section taken along the line I-I of Figure 3,

Figures 2 and 3 are, respectively, end and side elevations of the optical chamber illustrated in Figure 1, with the test strip holder removed,

Figure 4 illustrates the electronic circuitry of the glucometer,

Figures 5 to 10 illustrate the waveforms of the signals appearing at various terminals of the light source drive circuit and A/D circuit,

Figure 11 is a block circuit diagram of the data logger incorporated in the glucometer circuitry, and

Figures 12 and 13 respectively illustrate a plan view and a half section of a modified form of optical chamber.

Referring to Figures 1, 2 and 3 of the drawings, the optical chamber of the glucometer comprises a body 1 formed from two parts 2,3 joined together by screws 25 (not shown) engaging in holes 8 in the two parts. The body is preferably made of aluminium, the external surfaces of which have a dull-black anodised finish. Formed within the body are three passageways 4,5 and 6 constituting optical paths or guides. The first optical guide 4 is open at one end 7 and at its opposite end 30 mounts a light source in the form of an LED Q1. The latter is arranged to project light along the first



1 guide onto a test strip 9 positioned at the open end of  
the guide by means of a test strip holder 21. The  
second guide 5 intersects the first guide adjacent the  
open end 7 of the latter and has a photodiode sensor Q3  
5 for sensing reflectance mounted at its end remote from  
the first guide. The optical axis 12 of the second  
guide intersects the axis 11 of the first guide at the  
plane of the open end of the latter and is inclined at  
an angle of  $35^\circ$  with respect of the first optical axis  
10 11. A protective lens 13, for example, made from glass,  
is suitably located across the first and second optical  
guides adjacent the open end 7 of the first guide. The  
third optical guide 6 has its optical axis 14 disposed  
at right angles to the axis 11 of the first guide and  
15 intersects the latter at an intermediate position. A  
beam splitting lens 15, which may be formed from  
plastics material, is disposed in an inclined position  
across the first optical guide 4 with its surface  
adjacent the LED Q1 located on the point of  
20 intersection of the axes 11,14 of the first and third  
guides. The lens 15 reflects a fraction of the light  
projected along the first guide by the LED Q1, into the  
third optical guide 6 and onto a photodiode reference  
sensor Q2 mounted in the third guide, at its end remote  
25 from the first guide. The LED and photodiodes Q1,Q2,Q3  
are connected in the glucometer circuit by leads  
extending through holes 16 in the body 1 behind these  
components.

The body 1 has a head 17 at its end adjacent the  
30 open end 7 of the first optical guide 4 and a  
supporting leg 18 at its opposite end and, in use, it  
is stood on a suitable surface in the position shown in  
Figure 3. At its head end, the body has spaced opposed  
guide walls 19 having vertical guide ribs 20 on their

- inner surfaces. The holder 21 for supporting a test strip 9 in position at the open end 7 of the first optical guide 4 is in the form of a plug and is attached to the body by sliding it in between the guide walls 19, in engagement with the guide ribs 20. The holder is arranged to locate a test strip, which is slid into a slot 21a between the holder and optical chamber, across the open end of the first optical guide and press it into contact with the latter.
- The LED Q1 is preferably an infra-red LED emitting light in the region of 940 nm wavelength. The light emitted by Q1 travels down the first optical guide 4 and strikes the lens 15 which may, for example, be a .040 inch (approx. 10 mm) thick acrylic sheet.
- This lens is arranged to transmit 96% of the light projected by Q1 and to reflect 4% of this light onto the photodiode Q2. The optical guides 4,5,6 may be blackened with infra-red absorbing paint to eliminate most light coming at an angle of 10° or more thereby to force most of the incident light impinging on a test strip 9 to be as close as possible to 90°. Some light incident on the test strip is absorbed relative to colour and the remainder is reflected back into the optical guide 4 at various angles, depending on the surface of the strip and the pressure applied to the back of the strip by the strip holder 21. Most of the light is reflected back at an angle of 14° or less and is highly subject to the shine of the strip surface. However, the photodiode reflectance sensor Q3 is offset from the optical axis of the first guide 4 by 35° so that it is positioned out of the shine or halo area. By eliminating these shine effects, measurement of high absorbing colours is improved and glucose measurement in excess of 400 mg/dl is more accurate.

1           Since the light incident on photodiode reference  
sensor Q2 is independent of the colour of a test strip  
and is only a function of the incident light emitted by  
the LED Q1, it is used as a reflectance standard, as  
5 will hereinafter be more fully described, to give an  
output voltage corresponding to 100% reflectance.

The electronic circuit of the glucometer is  
illustrated in Figure 4 and basically comprises a  
central processing unit, conveniently, a microprocessor  
10 U6, such as that marketed by National Semiconductor  
Corporation under the Model No. COPS 444, a  
crystal-controlled clock circuit 22, a power supply and  
battery-run down detector circuit 23, LED drive and  
reflectance sensor circuits 24, A/D circuits 25, a  
15 visual display unit U10 and associated display driver  
circuit U8, a non-volatile memory U7 for calibration  
storage, a battery-backed, plug-in data logger 26, and  
an alarm circuit 27, all of which circuit elements are  
coupled to and controlled by the microprocessor U6.

20           The power supply circuit comprises a battery B,  
for example, a 9-volt battery, two transistors Q4,Q5,  
current limiting resistors R1,R2, a diode D1, a voltage  
regulator 28, a capacitor C2 connected across the  
battery and serving as a power supply filter, and  
25 manual 'on' and 'off' switches or keys S1,S2. The  
transistor Q4 serves to allow the microprocessor U6 to  
switch the power on and off in response to actuation of  
the keys S1 and S2, whilst Q5 serves as a buffer  
between the microprocessor and the switching transistor  
30 Q4. The voltage regulator 28 is a 5-volt regulator used  
to maintain the glucometer operating voltage within  
acceptable limits for the circuits. In this case, the  
regulator maintains a relative constant 5-volt power  
supply at its output.

1           Amplifier U9B is connected as a battery run-down  
detector and in conjunction with resistors R3,R4,R5 and  
R6 constantly monitors the input to the voltage  
regulator 28. Capacitor C1 serves as a filter. When the  
5   voltage input to the regulator 28 falls below 6 volts,  
the output of the amplifier U9B goes high, indicating  
to the microprocessor U6 that the battery B is weak.  
Consequently, the microprocessor stops further  
processing and the system is shut down. A battery  
10   warning indication may be displayed on the display unit  
U10 for a predetermined period, for example, 15  
seconds, before the system is shut down.

The drive circuit for the LED Q1 comprises an  
amplifier U3B which serves as a comparator and controls  
15   switching of a transistor Q6 connected in series with a  
current limiting resistor R20, the LED Q1 and an  
enabling transistor Q7, between the 5-volt power supply  
and ground. The transistor Q7 is controlled by the  
microprocessor U6, via a terminal D2 and an MOS  
20   transistor U4C. The latter is connected to the base of  
transistor Q7, via a current limiting resistor R18, and  
between the power supply and ground, via a current  
limiting resistor R19. Capacitor C13 serves as an LED  
drive filter.

25   A reference voltage is applied to the input  
terminal or pin 3 of the comparator amplifier U3B  
whilst a switching control signal derived from the  
reference sensor Q2 is applied to the other input pin  
2. The reference voltage is supplied by a voltage  
30   divider consisting of resistors R9 and R10 connected  
between the power supply and ground and having the  
junction between the resistors connected to the pin 3  
of amplifier U3B. This reference voltage is also  
applied to the input pin 5 of a reference amplifier U3A

1 connected as a voltage follower. The pin 5 and the  
output pin 7 of this amplifier are at the same  
approximate voltage. The resistor R21 connected to the  
output of the reference amplifier U3A serves only as a  
5 load resistor. The voltage signal at the output pin 7  
of the reference amplifier serves as a voltage  
reference for the A/D converter circuitry as will  
hereinafter be more fully described.

The cathode of the reference photodiode sensor Q2  
10 is connected to one input pin 2 of a reference sensor  
amplifier U2 having its other input pin 3 connected  
directly to ground. The output pin 6 of this amplifier  
is connected to a voltage divider network comprising  
resistors R13, R14, R15 and R16 which serves for  
15 calibration purposes. The control signal for the  
comparator amplifier U3B is obtained from an adjustable  
tap on the resistor R14, and resistor R13 and R14  
together adjust the fraction of the voltage output at  
the pin 6 of amplifier U2 which is applied to the input  
20 pin 2 of amplifier U3B. Capacitor C12 serves as a  
filter for the control signal whilst capacitor C14  
serves as a filter for the amplifier U2 output. Resistor  
R12 and capacitor C4 connected in parallel across the  
amplifier serve to integrate the amplifier output and  
25 reduce noise.

The cathode of the reflectance photodiode sensor  
Q3 is connected to one input pin 2 of a reflectance  
amplifier U1 having its other input pin 3 connected  
directly to ground. Resistor R8 is a load resistor  
30 connected to the output pin 6 of the reflectance sensor  
amplifier and resistor R7 and capacitor C3 connected in  
parallel across the amplifier from an integrating  
circuit which integrates the amplifier output and  
reduces noise. The pin 6 of the reflectance sensor

1 amplifier is connected to one input pin 10 of a chamber  
difference amplifier U3D having its other input pin 9  
connected via an amplifier gain resistor R17 to an  
adjustable tap on the resistor R16 of the voltage  
5 divider network connected to the output of the  
reference sensor amplifier U2. The resistor R11 is an  
amplifier gain resistor. The amplifier U3D is a fixed  
gain amplifier which amplifies the output of the  
reflectance sensor amplifier U1 by two times minus the  
10 voltage appearing at the adjustable tap of the resistor  
R16. The output of the chamber difference amplifier U3D  
is an analog signal representing the output of the  
reflectance sensor Q3 and is fed to the A/D circuitry  
for conversion into a digital signal representing the  
15 reflectance sensor output, as will hereinafter be more  
fully described.

The LED drive circuitry operates as follows. The  
reference voltage, for example, 1.146 volts, produced  
by the voltage divider R9,R10 is applied to the pin 3  
20 of the comparator amplifier U3B which compares it with  
the fraction of the output voltage of the reference  
sensor amplifier U2 applied to the pin 2 of the  
comparator amplifier. If the voltage appearing at the  
pin 2 of amplifier U3B is less than the voltage at pin  
25 3, the output voltage at pin 1 of U3B goes high and the  
transistor Q6 is switched on, thereby causing more  
current to flow through the LED Q1. The increased  
output of Q1 causes reference sensor Q2 to increase its  
voltage output, thereby causing the output of amplifier  
30 U2 to increase. When the voltage at pin 6 of the  
amplifier U2 is sufficient to cause the voltage at the  
pin 2 of the amplifier U3B to be larger than that at  
its pin 3, the output of the amplifier U3B goes low,  
turning off the LED Q1. The voltage at output pin 6 of

1 the amplifier U2 then begins to decay because no light  
is incident on the reference sensor Q2 and eventually  
decreases below a value sufficient to keep the  
potential at pin 2 of amplifier U3B above that of the  
5 pin 3, whereupon the transistor Q6 is turned on and the  
process is repeated (see Figs. 5 and 6). Consequently,  
the LED Q1 is continuously pulsed on and off (see Fig.  
7) with a frequency and pulse width sufficient to  
maintain the mean voltage at the pin 2 of the amplifier  
10 U3B at the reference voltage supplied by the voltage  
divider R9,R10 irrespective of temperature, LED  
efficiency or the sensitivity of reference photodiode  
Q2.

The resistor R14 is used to adjust the fraction  
15 of the voltage output at pin 6 of the amplifier U2 to  
be applied to the pin 2 of the comparator amplifier  
U3B. The higher the fraction, the less light is emitted  
by the led Q1 to enable control and the less light is  
incident on the reflectance sensor Q3 for a given  
20 reflector. Normally, a 90% reflector is inserted into  
the test chamber and the resistor R14 is adjusted such  
that LED Q1 emits sufficient light to cause the output  
of the reflectance sensor amplifier U1 to give a  
voltage corresponding to a 90% reflectance when 100% is  
25 equal to 1.146 volts, the reference voltage. The  
resistor R16 is used to adjust the dark reference. For  
this purpose, a 4.5% standard reflectance is inserted  
into the test chamber and the resistor R16 is adjusted  
until the correct voltage appears at the output pin 8  
30 of the chamber difference amplifier U3D. All optical  
chambers have stray reflectances, including those which  
are off the protective lens 13 in front of the test  
strip. These are usually greater than that received  
from a 4.5% reflector. Consequently, when calibrating

1 the low or dark reflectance reference, the offset reflectances and the effects of the amplifier's input offset voltages must be subtracted. The fixed gain amplifier U3D is used for this purpose.

5 Hence, the resistor R16 is used to subtract offset errors from the amplifiers and stray reflectances to enable an accurate low reflectance reading whilst the resistor R14 is used to calibrate the high reflectance reading. Since the whole system is  
10 a function of the reference voltage applied to the input pin 5 of the reference amplifier U3A and since all calibration voltages are derived from the output of the reference amplifier whose output is a function of this same reference voltage, the system is truly ratio  
15 metric and independent of battery voltage and absolute readings, as well as environmental conditions. The system is self-regulatory, requiring very short bursts of light current to enable a reflectance reading and thereby prolonging battery life.

20 The A/D converter circuitry 25 basically comprises a D-type flip-flop U5, an integrating amplifier U3C and a comparator amplifier U9A. The output of the reference amplifier U3A serves as a reference for both the analog system and the converter,  
25 thereby enhancing the ratio metric qualities of the overall system, and is connected to one terminal of two MOS transistors U4A,U4B, connected in series between the output pin 7 of U3A and ground and controlled by the D-type flip-flop U5. The capacitor C6 connected  
30 between the output pin 7 and ground serves as a reference follower filter. The flip-flop U5 is triggered by signals applied to its input D from the output of the comparator amplifier U9A.

The reflectance signal appearing at the output



1 pin 8 of the difference amplifier U3D is integrated by  
resistor R22 and capacitor C5 connected between the  
output pin 8 and ground and is applied to one input pin  
12 of the integrator amplifier U3C. The other input pin  
5 13 of this amplifier is connected to the junction of  
the two transistors U4A,U4B, via a filter resistor R23,  
and to the output pin 14 of the amplifier via an output  
filter capacitor C12. The output pin 14 of the  
integrating amplifier U3C is connected to one input pin  
10 5 of the comparator amplifier U9A by a filter resistor  
R24 which is also connected to ground by a capacitor C7  
and serving as a delay. The other input pin 6 of the  
amplifier U9A is connected to a reference voltage  
supplied by voltage divider resistors R25,R26 connected  
15 between the power supply and ground.

The A/D converter 25 is of the pulse width  
modulation type and is controlled by the microprocessor  
U6 which is fed with a digital signal via the terminal  
G3 connected to the output pin 2 of the flip-flop U5.  
20 When the reflectometer is taking a reading, the  
reflectance signal appearing at the output pin 8 of the  
chamber difference amplifier U3D is integrated by the  
resistor R22 and the capacitor C5 and is applied to the  
input pin 12 of the integrator amplifier U3C. Assuming  
25 that, at time 0, the state of the flip-flop U5 is pin 1  
= low and pin 2 = high, then the voltage at the pin 10  
of transistor U4A is zero. The voltage appearing at the  
pin 12 of amplifier U3C is initially zero, regardless  
of the output voltage on pin 8 of amplifier U3D and  
30 charges slowly to the output voltage of amplifier U3D.  
As the capacitor C5 charges, the voltage applied to pin  
12 of amplifier U3C exceeds the potential at pin 13,  
whereupon the output potential at pin 14 begins slowly  
to climb. When the voltage at pin 14 exceeds the

1 reference voltage developed by the voltage divider  
 R25,R26, the output pin 7 of the comparator amplifier  
 U9A goes high triggering flip-flop U5 and causing its  
 state to change to pin 1 = high, pin 2 = low, thereby  
 5 connecting the negative input of amplifier U3C to the  
 circuit reference voltage at pin 7 of amplifier U3A.  
 Amplifier U3C then commences to discharge until the  
 voltage at output pin 14 decays below that at input pin  
 6 of comparator amplifier U9A, whereupon the flip-flop  
 10 U5 is reset and the cycle repeats (see Figs. 8, 9 and  
 10).

The net result of this sequence of operations is  
 the production of a digital signal having a frequency  
 or pulse rate whose mark space ratio is a function of  
 15 the ratio of the reflectance sensor output signal at  
 the pin 8 of the amplifier U3D to the reference signal  
 at the output pin 7 of the reference amplifier U3A. The  
 microprocessor U6 counts the pulses appearing at the  
 pin 2 of the flip-flop U5 via terminal G3 and develops  
 20 a binary count according to the following formula:-

$$\text{Counts} = \frac{V_{\text{pin 8}}}{V_{\text{pin 7}}} \cdot 4096$$

The microprocessor consequently receives a  
 digital count directly related to the ratio of the  
 25 reflectance sensor output signal to the reference  
 voltage. On detecting a pulse count, the microprocessor  
 accesses a look-up table permanently stored in its read  
 only memory (ROM) and operates the display driver U8 to  
 display a corresponding glucose level on the visual  
 30 display unit U10.

The audio alarm 30, which may for example be 2  
 kHz piezoelectric disc, is excited by the  
 microprocessor U6 via transistors U4D and Q8. The  
 resistor R27 is a current limiting resistor. The alarm

1 tone is emitted each time a key is depressed, for  
example , to warn a user when to wipe a test strip 9  
and when a reading is complete.

The amplifiers U3A-D may be formed as parts of a  
5 single chip component as may also the MOS transistors  
U4A-D and the amplifiers U9A and B.

Upon depressing the 'on' key S1, the  
microprocessor U6 is initialised and immediately causes  
the alarm 30 to issue a short audio tone, for example,  
10 for 200 ms, to acknowledge that the 'on' key has been  
depressed. Initially, the microprocessor makes the  
following checks:-

1. Checks battery B voltage
2. Checks if calibration data is stored in the  
15 memory U7
3. Checks if the LED Q1 is functioning.

After these initial checks, the microprocessor  
checks to determine whether normal or factory  
calibration has been selected. Factory calibration  
20 selection is not available to the end user. If factory  
calibration is selected (by shorting the pin 5 on the  
microprocessor U6 to ground) the microprocessor  
initially checks all segments of the display U10 and  
external memory locations. The memory U7 is erased when  
25 this check is completed thus destroying all previous  
calibration data as well as stored glucose values. It  
then goes into a continuous reflectance test mode,  
whereby the display U10 constantly shows the A/D count  
of whatever it sees in the optical chamber. The system  
30 must be turned off to exit this mode. This mode is used  
to calibrate the glucometer and for long term accuracy  
tests.

If normal mode is selected, the microprocessor U6  
checks to determine if the free reflectance (no test

1 strip 9 in the chamber) is 37 +/- 1%. If it is below  
36%, but greater than 33%, the microprocessor indicates  
"CLEN" on the display U10. If it is below 33%, the  
microprocessor indicates "ER1" on the display. It then  
5 shuts down, indicating that the chamber is too dirty to  
get accurate measurements.

Assuming the glucometer passes the chamber clean  
test, the microprocessor U6 then checks to determine if  
calibration data is stored in the memory U7. If not,  
10 the processor displays "CAL" for one second and then  
indicates that a time sequence is next. This is the  
normal test sequence. It should be noted that the  
microprocessor has stored in its ROM the characteristic  
curve for glucose concentration versus percent  
15 reflectance. The calibration routine is required only  
to modify the curve to account for ageing and  
lot-to-lot variance. In most cases calibration is not  
required. The glucometer actually does not demand it  
and will continue to test even if modifying calibration  
20 data is not stored in the memory U7. If calibration  
data is stored in that memory, the microprocessor does  
not display "CAL" but goes directly to "SEC" (time  
indication) and awaits the depression of the time key  
S3. It then scans only the on/off keys S1, S2 and the  
25 time key S3. Upon depressing the time key, when the  
user has deposited blood on a test strip 9, the system  
immediately acknowledges the key depression by issuing  
a short tone on the audio alarm 30 and shows the time  
count on the display U10. At 58 seconds the system  
30 issues a short "get ready to wipe" audio tone; at 59  
seconds another short "get ready to wipe" audio tone is  
issued. At 60 seconds a longer 500 ms audio tone is  
issued, indicating the strip should be wiped. At 89  
seconds an audio tone is issued, indicating that it is

1 too late to insert the strip 9 if this has not already  
been done. At 90 seconds the LED Q1 is switched on by  
the microprocessor and the A/D converter is taken  
through one A/D conversion cycle to charge all A/D  
5 capacitors. At 91 seconds another A/D conversion is  
detected. On this occasion, the microprocessor U6  
retains the count and converts it to a ratio/count  
4096. The microprocessor then goes to the look-up  
tables to retrieve the corresponding glucose  
10 concentration value and checks the memory U7 to  
determine if the concentration should be modified. If  
there is no external calibration data written in the  
memory U7, the microprocessor causes the audible alarm  
30 to issue a short tone and displays the concentration  
15 on the visual display U10. At the same time, the  
reading obtained is written into the memory U7 and into  
the data logger 26. The data output to the data logger  
26 is in serial fashion with a "1" being 10 clock  
pulses long and "0" being 5 clock pulses long. The  
20 microprocessor also supplies the data logger with  
information as to whether received data is in mg/dl or  
mmol/litre.

The memory U7 is used to store the calibration  
data and a sequence of fifteen glucose readings. A  
25 reading is written into the memory if the calibration  
key S4 is depressed and the stored readings are  
accessible to the user simply by depressing the recall  
key S5. With each depression of the key S5, the  
microprocessor displays on U10 the reading stored in  
30 the memory U7 in a last in-first out sequence. The data  
is automatically stored in the memory U7 each time a  
reading is taken by the glucometer.

The glucometer circuit incorporates an automatic  
shut-down feature. If no key has been actuated within a

1 period of two minutes from actuation of the 'on' key  
S1, the microprocessor automatically turns off the  
power to enhance battery life. Automatic shut-down also  
occurs if a bad light source Q1 is detected or if the  
5 optical chamber is detected to be dirty.

As illustrated in Fig. 11, the data logger 26  
comprises a microprocessor 31, for example, an 8-bit  
microprocessor such as an MC68L05, a real time clock  
32, a RAM 33 and a ROM 34. After the real time clock 32  
10 has been set at a doctors office, the logger module is  
plugged into the glucometer. Upon insertion, the audio  
alarm 30 is actuated to issue a short tone to  
acknowledge successful insertion and "STO" (indicating  
storage) is briefly displayed on the visual display  
15 U10. Thereafter, whenever a reading is taken the  
glucometer microprocessor U6 issues a flag to the  
logger microprocessor 31 to accept input data. Data is  
supplied serially, in the format mentioned above, in  
straight binary followed by two parity bits. At this  
20 time, the glucometer displays above the glucose reading  
"STO" to signify that data is being stored. Upon  
successful transfer of glucose data, the logger  
microprocessor 31 reads the real time clock 32 and  
stores all data in the logger RAM 33. The latter and  
25 clock power are supplied from a self-contained battery.  
All other elements receive power from the glucometer  
power supply circuit 23. The ROM 34 stores the main  
logger sequence and logic programme and serves no  
function in storage of glucose/ time data. If the  
30 module is now unplugged from the glucometer and is  
inserted into a printer 35, the microprocessor 31  
begins to output data in ASQ1 II in the following  
format, last reading first:-

	<u>Date</u>	<u>Time</u>	<u>Reading</u>
1	4/21	3:03 p.m.	120
	4/20	4:05 p.m.	* 250
	4/19	4:00 p.m.	# 60

5 The "\*" and "#" are used to highlight high and low readings respectively.

The logger microprocessor 31 only reads storage cells in the RAM 33 containing data and prints "END" when it reaches an empty cell so as not to print all unused spaces in the RAM. Since the output format is an industry standard and module can be adapted to virtually all 20 or more column printers.

Figures 12 and 13 illustrate another embodiment of optical chamber for a glucometer, which chamber comprises duplicate sets of LEDs Q1, photodiode reference sensors Q2 and photodiode reflectance sensors Q3. Similarly to the first embodiment, it comprises a two-part body 40. The latter has two sets of passageways 41,42 constituting optical paths or guides, the first guide 41 of each set being open at one end 43 and having the LED Q1 at its opposite end, and the second guide 42 having an open end 44 adjacent the open end 43 of the first guide and having the reflectance sensor Q3 at its opposite end. Light from each LED Q1 is projected along the associated first guide 41 so as to impinge on a test strip (not shown) supported in a suitable holder (not shown) adjacent the open ends 43 of the guides 41. Each second guide 42 has its optical axis 45 inclined to the optical axis 46 of the associated first guide and intersects the axis of the first guide at a point in front of the open ends of the

1 guides and adjacent the position at which the test  
strip is supported. The optical axis 45 of each second  
guide is inclined at an angle of approximately  $35^\circ$  to  
the axis 46 of the associated first guide.

5 The reference sensors Q2 are mounted in a housing  
47 disposed above the first optical guides 41  
intermediate the ends thereof. The housing comprises a  
cavity 48 communicating with a cavity 49 formed along  
the first optical guides 41. The reference sensors Q2  
10 are mounted along optical axes 50 parallel to the  
optical axes 46 of the first guides and a small  
fraction of the light emitted by each LED Q1 is  
reflected onto the associated reference sensor Q2 by a  
beam splitting lens 51 mounted in an inclined position  
15 across the cavity 49 and, hence, relative to the first  
optical axes 46, and a reflector 52 mounted in an  
inclined position in the cavity 48.

Each set of LED and photodiodes Q1, Q2, Q3 may be  
connected in an LED drive and reflectance sensor  
20 circuit 24 as described above, utilising a multiplexer  
to interconnect this circuitry with the remainder of  
the glucometer system so as to produce reflectance  
readings from each reflectance sensor Q3.

Whilst particular embodiments have been  
25 described, it will be understood that modifications can  
be made without departing from the scope of the  
invention as defined by the appended claims. For  
example, the electronic system may be arranged  
automatically to store glucose readings in the memory  
30 U7 (15 readings) instead of as at present, requiring  
the user to depress a store key S4 to enable storage.  
The "CLEN" indicator and initial reflectance check upon  
power-on may be eliminated. This function, as presently  
programmed, requires the pressure plate pressing up



1 against the back of strip 9 to have a 34% reflectance  
(equivalent to 106 mg/dl of glucose). If no strip is in  
the strip holder unit, the latter could read 106 mg/dl  
giving user a false reading. This feature may be  
5 eliminated by making the pressure plate reflectance  
less than 20% thus giving a high reading if no strip 9  
is in the holder. The "ER1" function may be reduced to  
a simple lamp check, as opposed to checking if the  
optical chamber is dirty. It is difficult to access a  
10 dirty chamber by checking reflectance from the pressure  
plate. "ER1" may then be used to indicate a serious  
circuit or lamp malfunction. The "CAL" indicator may be  
eliminated if the unit does not have modifying CAL  
data. The system will still be capable of being  
15 calibrated by the user. However, it is believed this  
will be unnecessary and thus will keep the function if  
it is ever needed. This will depend upon ageing  
characteristics of the strip.

CLAIMS

- 1 1. An optical chamber for a reflectometer, comprising  
at least one light source (Q1) arranged to illuminate a  
test specimen (9) via a first optical path (4,41) and  
at least one reflectance photosensor (Q3) for detecting  
5 light reflected from said test specimen, characterised  
in that the reflectance photosensor (Q3) is disposed  
along a second optical path (5,42) having its optical  
axis (12,45) inclined to the optical axis (11,46) of  
the first optical path (4,41) and intersecting said  
10 first optical axis (11,46) at or adjacent the test  
specimen (9), whereby the photosensor (Q3) detects  
random reflections from the test specimen.
2. An optical chamber according to claim 1,  
characterised in that the optical axis (12,45) of the  
15 second optical path is inclined to the optical axis  
(11,46) of the first optical path at an angle of at  
least 20° and, preferably at an angle of approximately  
35°.
3. An optical chamber according to claim 1 or 2,  
20 characterised in that the test specimen (9) is in the  
form of a test strip, and means is provided for  
locating said test strip along the first optical path  
(4) with the plane of said strip disposed substantially  
perpendicular to the first optical axis (11), and  
25 further characterised in that a protective lens device  
(13) is disposed across the first and second optical  
paths (4,5) adjacent the position at which the test  
strip (9) is located.
4. An optical chamber according to claim 1, 2 or 3,  
30 characterised by at least one reference photosensor  
(Q2) disposed along a third optical path (6,48), for  
example, having its optical axis (14) substantially

- 1 perpendicular to the optical axis (11) of the first  
optical path (4), and beam splitter means (15,51)  
arranged to reflect a minor fraction of the light  
emitted by said at least one light source (Q1), along  
5 the third optical path (6,48) and onto the reference  
sensor (Q2) whilst transmitting a major fraction of the  
light so as to impinge on the test specimen (9).
5. An optical chamber according to claim 4,  
characterised by a drive circuit for the or each light  
10 source (Q1) which is responsive to a control signal  
derived from the associated reference sensor (Q2) and  
which operates the light source to maintain the control  
signal at a generally constant level.
6. An optical chamber according to claim 4 or 5,  
15 characterised in that the or each light source (Q1) is  
a light emitting diode and the sensors (Q2,Q3) are  
photodiodes.
7. A reflectometer including an optical chamber having  
at least one light source (Q1) for illuminating a test  
20 specimen (9), and at least one reflectance photosensor  
(Q3) responsive to light reflected from the test  
specimen to produce a reflectance signal corresponding  
to the reflectance of the specimen, characterised by at  
least one reference photosensor (Q2) responsive to a  
25 fraction of the light emitted by said at least one  
light source (Q1), and a drive circuit (24) for the or  
each light source which is responsive to a control  
signal derived from the associated reference sensor  
(Q2) and which operates the light source (Q1) so as to  
30 maintain said control signal generally at a constant  
level.
8. A reflectometer according to claim 7, characterised  
in that the drive circuit comprises comparator means  
(U3B) which compares the control signal derived from

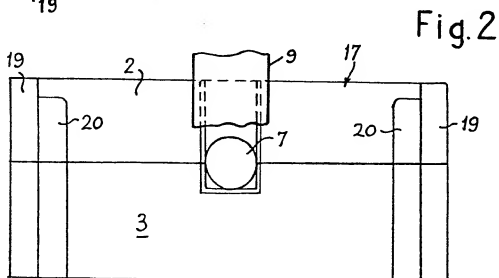
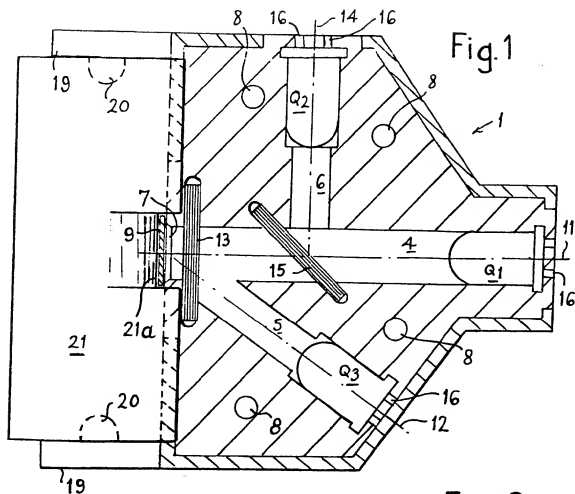
- 1 the reference sensor (Q2) with a reference signal, and  
a switching device (Q6) for controlling the light  
source (Q1) and which is responsive to the comparator  
means, whereby to actuate the light source so as to  
5 maintain the control signal generally at a constant  
level, for example, the level of the reference signal.
9. A reflectometer according to claim 7 or 8,  
characterised by a reference sensor amplifier (U2) for  
the reference photosensor (Q2), a first integrating  
10 circuit (R12,C14) for integrating the output of said  
reference sensor amplifier, and a first voltage divider  
(R13-R16) connected to the output of said amplifier,  
said control signal for the drive circuit being derived  
from said first voltage divider.
- 15 10. A reflectometer according to claim 7, 8 or 9,  
characterised by means (25) for producing a digital  
reflectance signal corresponding to the reflectance  
sensor output.
11. A reflectometer according to claim 10,  
20 characterised by a reflectance sensor amplifier (U1)  
for the reflectance sensor (Q3), a second integrating  
circuit (R7,C13) for integrating the output of said  
reflectance sensor amplifier, and means (25) for  
processing the output signal of said reflectance sensor  
25 amplifier to produce a digital reflectance signal.
12. A reflectometer according to claim 10 or 11,  
characterised in that the means for producing a digital  
reflectance signal includes an analog-to-digital  
converter (25) which compares an analog reflectance  
30 signal derived from the reflectance sensor output with  
a reference signal and produces a pulse train having a  
pulse rate corresponding to the analog reflectance  
signal.
13. A reflectometer according to claim 12,

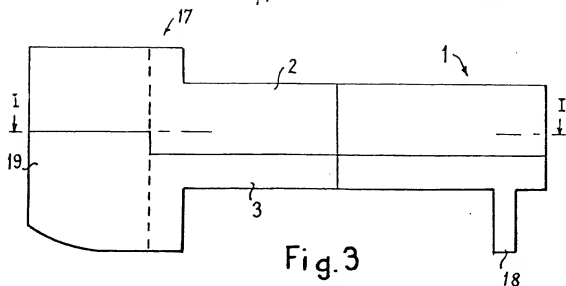
1 characterised by a fixed gain amplifier (U3D) having  
inputs connected to the output of the reflectance  
sensor amplifier (U1) and the first voltage divider  
(R13-R16), respectively, said analog-to-digital  
5 converter (25) being connected to the output of the  
fixed gain amplifier, and the connection of the drive  
circuit to the first voltage divider being adjustable  
so as to determine the light standard reflectance and  
the connection of the fixed gain amplifier (U3D) to the  
10 first voltage divider being adjustable to determine the  
dark standard reference.

14. A reflectometer according to claim 12 or 13,  
characterised by a second voltage divider (R9,R10) for  
producing the reference signal, and a reference  
15 amplifier (U3A), said second voltage divider being  
connected to the drive circuit and the reference  
amplifier, and the output of said reference amplifier  
(U3A) being connected to the analog-to-digital  
converter (25).

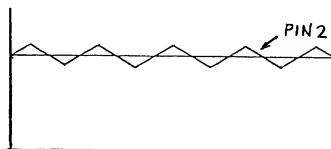
20 15. A reflectometer according to claim 14, wherein the  
analog-to-digital converter (25) compares the analog  
reflectance signal and the reference signal derived  
from the reference amplifier (U3A) and produces a  
digital reflectance signal in the form of a pulse train  
25 having a pulse rate corresponding to the analog  
reflectance signal.

16. A reflectometer according to any preceding claim  
10 to 15, characterised by central processing means  
(U6) for processing the digital reflectance signal and  
30 producing a measurement of reflectance.



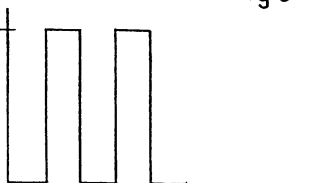


U3B  
PINS 3 AND 2  
V<sub>REF.</sub>



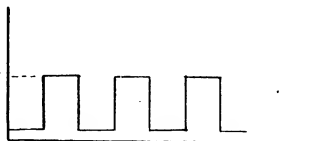
U3B PIN 1  
V<sub>cc</sub> - 1.5

Fig. 6



Q1 ANODE  
1.2 VOLTS

Fig. 7



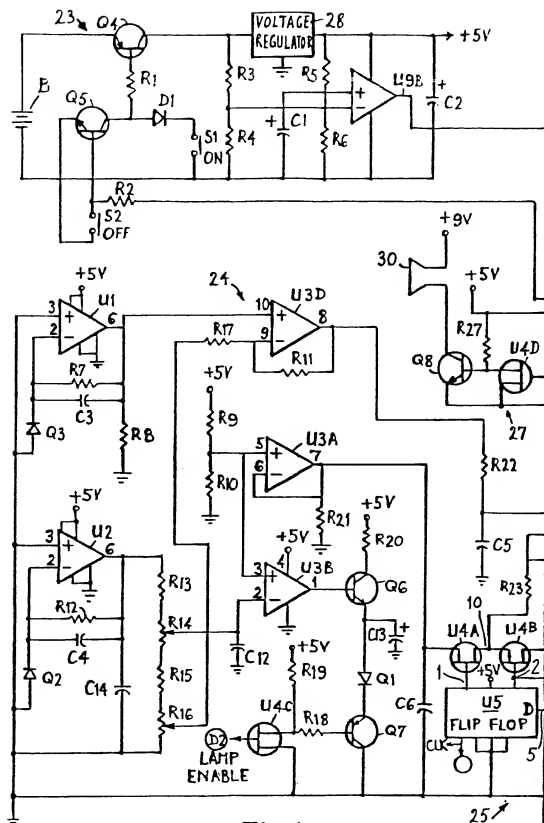


Fig.4



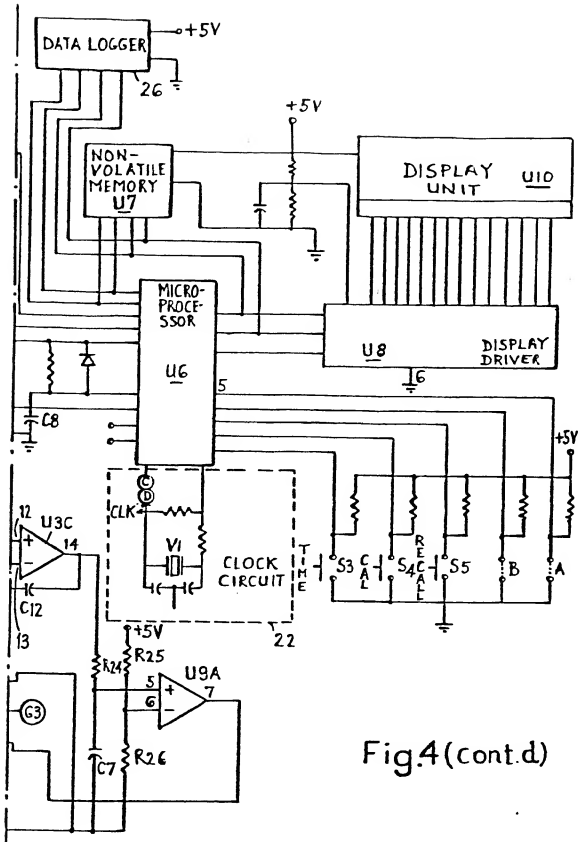


Fig.4(cont.d)

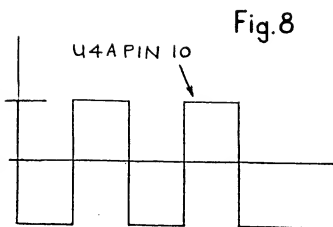
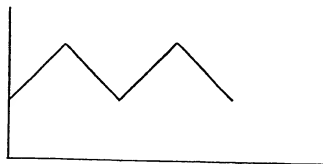
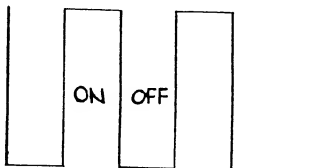
U3C PIN 12 AND 13ASSUMES  $V_{OUT} =$  $\frac{1}{2} V_{REF}$   $V_{REF}$ U3D PIN 8  $V_{OUT}$ U3C PIN 14

Fig.9

U9A PIN 7  $V_{CC} = 1.5$ 

Fig.10



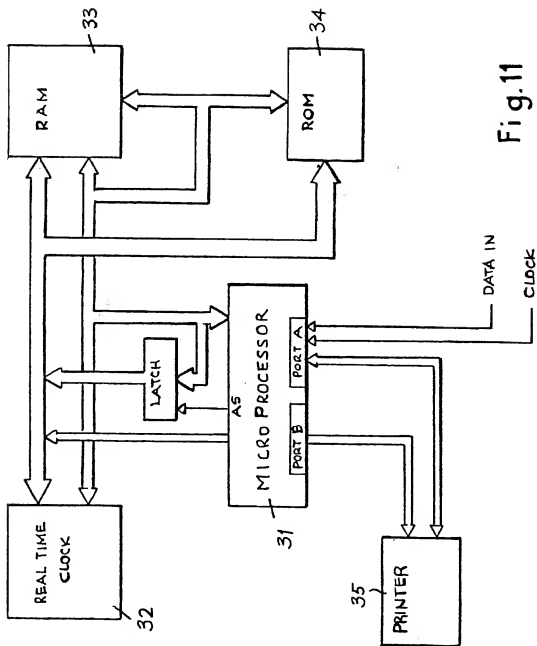


Fig. 11

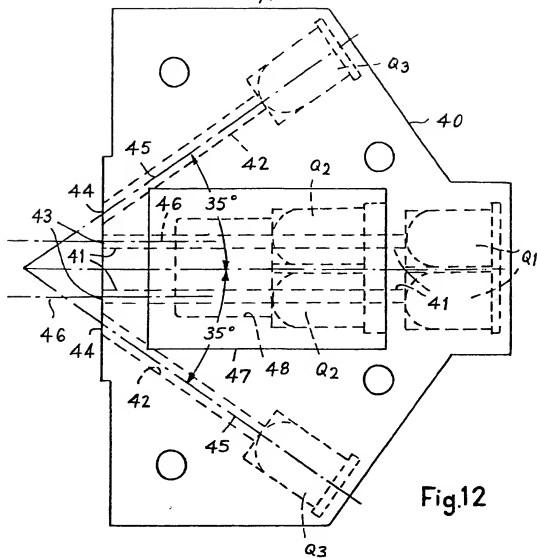


Fig.12

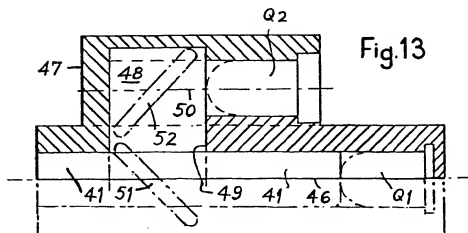


Fig.13

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

### **IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**